

EX



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,671	12/10/2001	Otfried Kistner	V-262.00	2215
7590 10/12/2005				
Baxter healthcare Corporation P.O. Box 15210 Irvine, CA 92614			EXAMINER CHEN, STACY BROWN	
			ART UNIT 1648	PAPER NUMBER
DATE MAILED: 10/12/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/006,671

**Applicant(s)**

KISTNER ET AL.

**Examiner**

Stacy B Chen

**Art Unit**

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,7-9,11,14-17 and 27-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,7-9,11,14-17 and 27-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 5, 2005 has been entered. Claims 1, 2, 4, 7-9, 11, 14-17 and 27-31 are pending and under examination.

### ***Claim Rejections - 35 USC § 103***

2. Claims 1, 2, 4, 7-9, 11, 14-17 and 27-31 remain rejected under 35 U.S.C., 103(a) as unpatentable over Dubensky Jr. *et al.* (5,789,245) in view of Yu *et al.* (reference AM from IDS), for reasons of record. The claims as amended are drawn to a method for producing purified Ross River Virus (RRV) antigen/immunogenic compositions comprising the steps of infecting a cell culture with RRV, incubating the infected cell culture, harvesting the RRV produced, filtering through two filters and purifying the virus antigen. The first filter has a pore size of between about 0.3 and about 1.5 microns. The second filter has a pore size of between about 0.1 and about 0.5 microns. Claims 27-31 are drawn to limitations of the methods the first filter is based on a positively charged matrix and the second filter is based on a hydrophilic matrix. The method further comprises treating the filtered virus with a nucleic acid degrading agent. The examiner notes with appreciation the explanation of Table 1.

Art Unit: 1648

Applicant's arguments have been carefully considered but fail to persuade withdrawal of the rejection. Applicant's substantive arguments are primarily directed to the following:

- Applicant asserts that the instantly claimed method results in a surprisingly pure RRV antigen *intermediate* through filtering without any substantial reduction in virus titer. The preparation is about 97% pure after just two filtration steps. Applicant argues that Dubensky's method does not result in a preparation of RRV that is about 97% pure.
  - In response to Applicant's argument, the method disclosed by Dubensky uses two filtration steps. Dubensky teaches a large-scale method for producing alphavirus vectors by infecting VERO cells (col. 2, line 5) and incubating and propagating in a bioreactor. The media is passed through a 0.8-micron filter and then through a 0.65-micron filter to clarify the crude alphavirus particles.
  - The difference between Dubensky and the instant claims is the size of the second filter, a 0.15 micron difference. Given the similarity of the methods and the known size of RRV, one would have achieved the same result as Applicant when using the two filtering steps. The intermediate virus preparation would have been about 97% pure, whether anyone recognized that or not.
- Applicant argues that Dubensky refers to the intermediate as "crude". Applicant argues that the skilled artisan would not consider Dubensky's "crude" preparation as about 97% pure. Applicant argues that the further purification steps cited in the claims do not substantially purify the virus more than the filtration steps.
  - In response to Applicant's argument, it appears that Applicant is inferring that Dubensky was relying on further purification steps to achieve a pure preparation

Art Unit: 1648

of virus. While this may be true, the instant claims are directed to methods involving two filtration steps followed by further purification. Had one of ordinary skill performed Dubensky's method with RRV, the virus intermediate would have necessarily been "about 97% pure". While Dubensky did not appreciate this, the method steps are similar to Applicant's method. Therefore, anyone practicing Dubensky's method with RRV would be performing Applicant's invention, regardless of the description of the virus intermediate as "crude" or "pure". Following Dubensky's teachings, one would have obtained the virus intermediate and purified it further. The same teachings are present in the instant claims.

- Applicant argues that Dubensky's disclosure is of an entirely different technical field (recombinant vectors) than Yu (purified antigen). Applicant argues that Dubensky clarifies using filtration, while Applicant clarifies using separation.
  - In response to this argument, the claims do not exclude viral vectors, nor do they distinguish between the steps of clarification from Dubensky's steps. The claims do not recite any language about clarification being performed by separation. The specification does not teach how such an obvious alternative step would result in a structurally different product or preparation.
- Applicant also argues that one of ordinary skill in the art would recognize that changing filter size would not directly correlate to virus particle size. Applicant argues that even small changes, in this case 0.15 microns, can be a patentable difference. Applicant argues that Dubensky does not suggest using a smaller filter.

Art Unit: 1648

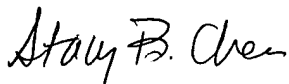
- In response, while Dubensky does not suggest altering the size of the second filter to 0.5 microns, Dubensky suggests the purification of RRV vectors. One of ordinary skill in the art would have known the size of RRV and adjusted accordingly in order to separate from unwanted components. Applicant argues that there is no correlation between virus size and pore size in this instance. Evidence of sensitivity of pore size in relation to virus size would be useful. Lacking any evidence to the contrary, it would have been well within the skill of the ordinary artisan to adjust the filter size to better accommodate the virus size.

### *Conclusion*

3. No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



Stacy B. Chen  
October 7, 2005